

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

Listing of Claims

1. (Presently Amended) A composition comprising the a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan, the composition formed from the steps of a method comprising:
 - a.—forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients consisting of phenylephrine, pyrilamine, and dextromethorphan in a first solvent to form a first solution, wherein said active pharmaceutical ingredients are dissolved under conditions that will not cause decomposition of the active pharmaceutical ingredients;
 - b.—forming a dispersion by mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion;
 - c.—transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of said active pharmaceutical ingredients;
 - d.—combining substances selected from the group consisting of preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents and pH adjusting agents the solution and the dispersion to form a liquid pharmaceutical carrier tannate salts of the active pharmaceutical ingredients; and
 - e.—combining at least a portion of the second solution to the liquid pharmaceutical carrier to produce a liquid dosage form the tannate salts without

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

isolation or purification with at least one suspending agent to produce a homogeneous suspension including pharmaceutically active tannate salts, the homogeneous suspension being in an amount including a plurality of dosage units, the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.

2. (Presently Amended) The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of about 0.05% to about 25.0% by weight.
3. (Presently Amended) The composition of claim 1 wherein the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, hydrochloride chloride, hydrobromide bromide, acetate, and sulfate, and combinations thereof.
4. (Original) The composition of claim 1 wherein the tannic acid is natural or synthetic.
5. (Presently Amended) The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

6. (Presently Amended) The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.

7. (Presently Amended) The composition of claim 1 wherein the tannic acid is present in a range of about 0.01% to about 30.0% by weight.

8. (Original) The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.

9. (Presently Amended) The composition of claim 1 wherein the tannic acid ~~and~~ to the active pharmaceutical ingredients ~~are~~ is present by weight in a ratio in the range of 1:~~1~~
2:1 to 10:1.

10. (Presently Amended) The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.

11. (Presently Amended) The composition of claim 1 wherein the suspending agent is xanthan gum and is present in a range of about 0.5% to about 10.0% by weight.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

12. (Presently Amended) The composition of claim 1 wherein the sweetening agents include sucrose present in a range of about 5.0% to about 50.0% by weight, and sucralose and magnasweet MM-100 are each present in a range of about 0.01% to about 3.0% by weight.

13. (Presently Amended) The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of about 0.01% to about 2.0% by weight.

14. (Presently Amended) The composition of claim 1 wherein the second solvent for the dispersion is water and is present in a range of about 10.0% to about 85.0% by weight.

15. (Presently Amended) The composition of claim 1 wherein said second the solvent for the dispersion is glycerin and is present in a range of about 2.5% to about 20.0% by weight.

16. (Presently Amended) The composition of claim 1 wherein the preservative is methylparaben and is present in a range of about 0.01% to about 1.0% by weight.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

17. (Presently Amended) The composition of claim 1 wherein the pH adjusting agents are sodium benzoate, citric acid, and sodium citrate, and are each present in a range of about 0.05% to about 1.0% by weight.

18. (Presently Amended) The composition of claim 1 wherein the anti-caking anticaking agent is MAS magnesium aluminum silicate and is present in the range of about 0.5% to about 10.0% by weight.

19. (Presently Amended) The composition of claim 1 wherein the pH of said liquid dosage form is in a range of about 3.5 to about 6.5.

20. (Presently Amended) The composition of claim 1 wherein the pharmaceutically active tannate salts are pyrilamine tannate present at about 30mg 30 mg, phenylephrine tannate present at about 12.5mg 12.5 mg, and dextromethorphan tannate present at about 25 mg.

21. (Original) The composition of claim 19 wherein said liquid dosage form is a suspension.

22. (Cancelled)

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

23. (Cancelled)

24. (Cancelled)

25. (Cancelled)

26. (Cancelled)

27. (Cancelled)

28. (Cancelled)

29. (Cancelled)

30. (Cancelled)

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

31. (Presently Amended) A composition comprising active pharmaceutical ingredients selected from the group consisting of phenylephrine, pyrilamine, and dextromethorphan, the composition formed from the steps of:

a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan, the composition formed from a method comprising:

- a.—forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients consisting of phenylephrine, pyrilamine, and dextromethorphan in a first solvent to form a first solution, wherein said active pharmaceutical ingredient are dissolved under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- b.—forming a powder mixture by mixing a dispersing agent, diluent and tannic acid to form a first powder mixture;
- c.—combining the transferring at least a portion of the first solution to and the first powder mixture, to form tannate salts of said the active pharmaceutical ingredients in a granulate; and
- d.—combining the tannate salts without isolation or purification with at least one tablet excipient to prepare a homogeneous granulation including pharmaceutically active tannate salts, the homogeneous granulation being in an amount to include a plurality of dosage units, the homogeneous granulation being homogeneous in amounts

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units granulate with one or more substances selected from the group consisting of diluents, dry binding/matrix-forming agents, binding solutions, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents, and excipients; and

f. ——processing the granulate into solid dosage forms.

32. (Presently Amended) The process composition of claim 31 wherein the active pharmaceutical ingredients are free bases or salts selected from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate, and combinations thereof.

33. (Presently Amended) The process composition of claim 31 wherein the tannic acid is natural or synthetic.

34. (Presently Amended) The process composition of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

35. (Presently Amended) The process composition of claim 31 wherein the solvents are selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.

36. (Presently Amended) The process composition of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol, and combinations thereof, and is present in a concentration of about 1.0% to about 75.0%.

37. (Presently Amended) The process composition of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, pregelatinized starch, potato starch, polyvinylpyrrolidone and xanthan gum, and combinations thereof, and is present in a concentration of about 0.1% to about 20.0%.

38. (Presently Amended) The process composition of claim 37 wherein the binder solution further comprises a solvent.

39. (Presently Amended) The process composition of claim 38 wherein the solvent is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

40. (Presently Amended) The process composition of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone, and combinations thereof, and each is present at a concentration of about 0.1% to about 20.0%.

41. (Presently Amended) The process composition of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple, and combinations thereof, and each is present at a concentration of about 0.01% to about 2.0%.

42. (Presently Amended) The process composition of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol, magnasweet MM-100, and sucralose, and combinations thereof, and each is present at a concentration of about 0.01% to about 40.0%.

43. (Presently Amended) The process composition of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry, and combinations thereof, and is present in a concentration of about 0.01% to about 3.0%.

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

44. (Presently Amended) The process composition of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.

45. (Presently Amended) The process composition of claim 31 wherein the tannic acid is present in the range of about 0.05% to about 30.0% by weight.

46. (Presently Amended) The process composition of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.

47. (Presently Amended) The process composition of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio of 1:1 2:1 to 10:1.

48. (Presently Amended) The process composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg 30 mg, phenylephrine tannate present at 25mg 25 mg, and dextromethorphan tannate present at 25 mg.

49. (Cancelled)

Application Serial No. 10/645,977
Response to Office Action and Amendment dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

50. (Cancelled)

51. (Cancelled)

52. (Cancelled)

Application Serial No. 10/645,977
Response dated August 14, 2006
Application Filed August 22, 2003
Atty. Docket: PEDI-16

53. (Presently Amended) A homogeneous composition comprising tannate salts being formed by a method comprising:

a plurality of active pharmaceutical ingredients comprising tannate salts, the homogeneous composition being in an amount including a plurality of dosage units, the homogeneous composition being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units, the homogeneous composition being formed by a method comprising:

a.—dissolving the salt or free base of active pharmaceutical ingredients selected from the group consisting essentially of phenylephrine, pyrilamine, and dextromethorphan in a first solvent to form a first solution, wherein said active pharmaceutical ingredients are dissolved at a temperature and pH value that will not cause decomposition of the active pharmaceutical ingredients;

b.—mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion; and

c.—transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients without isolation or purification.